



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	19K5.R4
True Name	Porcine Circovirus Vaccine, Type 2, Killed Baculovirus Vector
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	
Date of Compilation Summary	December 02, 2020

Disclaimer: Do not use the following studies to compare one product to another. Slight differences in study design and execution can render the comparisons meaningless.

Study Type	Efficacy														
Pertaining to	Porcine Circovirus Vaccine, Type 2, Killed Baculovirus Vector														
Study Purpose	Demonstration of efficacy														
Product Administration	Single intramuscular administration of vaccine. ORF2 gene of strain PCV2d.														
Study Animals	Cesarian-derived, colostrum deprived (CDCD) pigs, 21 days of age; divided into groups (25 Control, 25 Vaccinate)														
Challenge Description	Virulent PCV2d challenge virus administered to control and vaccine pigs 28 days following vaccination														
Interval observed after challenge	Daily for 28 days post-challenge. Necropsy conducted at time of death or end of the challenge period. Tissue samples collected at necropsy for histopathology and immunohistochemistry: tonsil, tracheobronchial lymph node (TBLN), mesenteric lymph node (MLN), and iliac lymph node (ILN)														
Results:	<p>Summary of Results</p> <table border="1"> <thead> <tr> <th></th> <th>Lymphoid Depletion +/-total (%)</th> <th>Lymphoid Colonization +/-total (%)</th> <th>Viremia</th> </tr> </thead> <tbody> <tr> <td>Control Affected</td> <td>22/24 (92%)</td> <td>24/24 (100%)</td> <td>24/24 (100%)</td> </tr> <tr> <td>Vaccinate Affected</td> <td>0/25 (0%)</td> <td>0/25 (0%)</td> <td>2/25 (8%)</td> </tr> </tbody> </table> <p>Lymphoid Depletion Criteria: Negative (-) = Normal, no lymphoid depletion present Positive (+) = Mild, moderate or severe depletion</p> <p>Lymphoid Colonization (IHC) Criteria: Negative (-) = Zero lymphoid cells with PCV2 antigen staining Positive (+) = Lymphoid follicles have cells with PCV2 antigen staining</p> <p>Viremia Criteria: Negative (-) if $\leq 10^4$ genomic equivalents per mL Positive (+) if $> 10^4$ genomic equivalents per mL</p>				Lymphoid Depletion +/-total (%)	Lymphoid Colonization +/-total (%)	Viremia	Control Affected	22/24 (92%)	24/24 (100%)	24/24 (100%)	Vaccinate Affected	0/25 (0%)	0/25 (0%)	2/25 (8%)
	Lymphoid Depletion +/-total (%)	Lymphoid Colonization +/-total (%)	Viremia												
Control Affected	22/24 (92%)	24/24 (100%)	24/24 (100%)												
Vaccinate Affected	0/25 (0%)	0/25 (0%)	2/25 (8%)												

Raw Data:

ILN = Iliac Lymph Node

MLN = Mesenteric Lymph Node

TBLN = Tracheobronchial Lymph Node

Individual Control Pig Lymphoid Tissue Pathology Results

Pig ID	Lymphoid Depletion				Lymphoid IHC			
	ILN	MLN	TBLN	TONSIL	ILN	MLN	TBLN	TONSIL
1	-	+	-	-	+	+	+	+
7	-	+	+	-	+	+	+	+
10	-	+	-	-	+	+	+	+
12	+	-	+	+	+	+	+	+
16	+	+	+	+	+	+	+	+
21	-	-	+	-	+	+	+	+
23	+	-	-	-	+	+	+	+
24	+	+	+	+	+	+	+	+
25	+	+	+	+	+	+	+	+
28	-	+	+	+	+	+	+	+
49	-	-	+	+	+	+	+	+
51	+	+	+	+	+	+	+	+
31	+	+	-	-	+	+	+	+
35	-	-	-	-	-	+	+	+
36	+	+	+	+	+	+	+	+
41	+	+	+	+	+	+	+	+
54	-	+	+	-	+	+	+	+
13	+	-	-	-	+	+	+	+
14	-	-	+	+	+	+	+	+
15	+	-	-	-	+	+	-	-
46	-	-	-	-	+	-	-	-
38	+	+	-	-	+	+	+	+
55	+	-	-	+	+	+	+	+
56	-	+	-	-	+	+	-	+

Individual Vaccinated Pig Lymphoid Tissue Pathology Results

Pig ID	Lymphoid Depletion				Lymphoid IHC			
	ILN	MLN	TBLN	TONSIL	ILN	MLN	TBLN	TONSIL
3	-	-	-	-	-	-	-	-
9	-	-	-	-	-	-	-	-
4	-	-	-	-	-	-	-	-
6	-	-	-	-	-	-	-	-
11	-	-	-	-	-	-	-	-
17	-	-	-	-	-	-	-	-
18	-	-	-	-	-	-	-	-
19	-	-	-	-	-	-	-	-
22	-	-	-	-	-	-	-	-
26	-	-	-	-	-	-	-	-
29	-	-	-	-	-	-	-	-
30	-	-	-	-	-	-	-	-
50	-	-	-	-	-	-	-	-
33	-	-	-	-	-	-	-	-
34	-	-	-	-	-	-	-	-
40	-	-	-	-	-	-	-	-
52	-	-	-	-	-	-	-	-
53	-	-	-	-	-	-	-	-
43	-	-	-	-	-	-	-	-
45	-	-	-	-	-	-	-	-
47	-	-	-	-	-	-	-	-
48	-	-	-	-	-	-	-	-
37	-	-	-	-	-	-	-	-
39	-	-	-	-	-	-	-	-
57	-	-	-	-	-	-	-	-

Individual Pig Viremia Results--PCR

Controls				
Pig ID	Study Day			
	35	42	49	56
1	+	+	+	+
7	+	+	+	+
10	+	+	+	+
12	+	+	+	+
13	+	+	+	+
14	+	+	+	+
15	+	+	+	+
16	+	+	+	+
21	+	+	+	+
23	+	+	+	+
24	+	+	+	+
25	+	+	+	NA
28	+	+	+	+
31	+	+	+	+
35	+	+	+	+
36	+	+	+	+
38	+	+	+	+
41	+	+	+	+
46	+	+	+	+
49	+	+	+	+
51	+	+	NA	NA
54	+	+	+	+
55	+	+	+	+
56	+	+	+	+

Vaccinates				
Pig ID	Study Day			
	35	42	49	56
3	-	-	-	-
4	-	-	-	-
6	-	-	-	-
9	-	-	-	-
11	-	-	-	-
17	-	-	-	-
18	-	-	-	-
19	-	-	-	-
22	-	-	-	-
26	-	-	-	-
29	-	+	-	-
30	-	-	-	-
33	-	+	-	-
34	-	-	-	-
37	-	-	-	-
39	-	-	-	-
40	-	-	-	-
43	-	-	-	-
45	-	-	-	-
47	-	-	-	-
48	-	-	-	-
50	-	-	-	-
52	-	-	-	-
53	-	-	-	-
57	-	-	-	-

Positive (+) if $> 10^4$ genomic equivalents per mL
 Negative (-) if $\leq 10^4$ genomic equivalents per mL
 NA = sample not available

**USDA Approval
Date**

September 14, 2017

Study Type	Safety																																				
Pertaining to	All																																				
Study Purpose	To demonstrate safety under field conditions																																				
Product Administration	Single intramuscular administration																																				
Study Animals	1355 pigs at 10 - 30 days of age, (≥ 200 pigs from each of three different geographical locations were vaccinated, and a similar number at each site were not vaccinated for comparison)																																				
Challenge Description	Not applicable																																				
Interval observed after challenge	Pigs were observed immediately following vaccination and then for 14 days following vaccination. No challenge was conducted.																																				
Results	<p>Observations of Vaccinated Pigs:</p> <table border="1"> <thead> <tr> <th>Clinical Observation ^a</th> <th>MO Site N=244</th> <th>NE Site N=229</th> <th>IN Site N=207</th> </tr> </thead> <tbody> <tr> <td>None ^b</td> <td>241</td> <td>210</td> <td>193</td> </tr> <tr> <td>Poor Condition ^c</td> <td>0</td> <td>15</td> <td>0</td> </tr> <tr> <td>Dead ^d</td> <td>3</td> <td>2</td> <td>3</td> </tr> <tr> <td>Scours</td> <td>0</td> <td>1</td> <td>10</td> </tr> <tr> <td>Lame</td> <td>0</td> <td>1</td> <td>0</td> </tr> <tr> <td>Swollen Joint(s)</td> <td>2</td> <td>0</td> <td>0</td> </tr> <tr> <td>Cough</td> <td>0</td> <td>0</td> <td>1</td> </tr> <tr> <td>Skin Abnormalities ^e</td> <td>0</td> <td>1</td> <td>1</td> </tr> </tbody> </table> <p>^a Pigs may have exhibited more than one clinical observation. ^b For an observation of “None” a pig had to be without clinical observations for the entire 14 days of the study. ^c Observations of “Poor Condition” included: thin starve, small thin, small, gaunt, gaunt weak, and thin. ^d Observation of “Dead” included: Dead, Died, and Euthanized. ^e Observation of “Skin Abnormalities” included: scabbed knees and skin spots</p>	Clinical Observation ^a	MO Site N=244	NE Site N=229	IN Site N=207	None ^b	241	210	193	Poor Condition ^c	0	15	0	Dead ^d	3	2	3	Scours	0	1	10	Lame	0	1	0	Swollen Joint(s)	2	0	0	Cough	0	0	1	Skin Abnormalities ^e	0	1	1
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Swollen Joint(s)	2	0	0																																		
Cough	0	0	1																																		
Skin Abnormalities ^e	0	1	1																																		

	Observations of Control Pigs:			
	Clinical Observation ^a	MO Site N=241	NE Site N=228	IN Site N=206
	None ^b	237	209	195
	Poor Condition ^c	0	13	0
	Dead ^d	4	2	1
	Scours	0	0	9
	Lame ^e	0	3	1
	Swollen Joint(s)	2	0	0
	Hernia ^f	0	2	0
	^a Pigs may have exhibited more than one clinical observation. ^b For an observation of “None” a pig had to be without clinical observations for the entire 14 days of the study. ^c Observations of “Poor Condition” included: thin, gaunt, gaunt/weak, and gaunt-purple ears. ^d Observation of “Dead” included: dead, died, and euthanized. ^e Observation of “Lame” included: lame, sore right front foot, and shoulder ^f Observation of “Hernia” included: hernia and surgery.			
USDA Approval Date	April 5, 2006			